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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,925	03/10/2004	Wumin Li	AM 101333	3270

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,925	LI ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on April 10, 2006 is acknowledged. Newly added claims 22-23 are pending and under consideration. Claims 1-21 have been canceled.

Applicant's amendment after-final necessitates a new art rejection and, therefore, the finality of the prior office action is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

1. In view of applicants' response the rejection of claim 20 under 35 U.S.C. 102(b), Finlay et al on page 4, paragraph 4 is withdrawn.

2. In view of applicants' response the rejection of claim 21 under 35 U.S.C. 103(a) over Finlay et al in view of Brashears et al on page 5, paragraph 5 is withdrawn.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle et al (U.S. Patent 5,965,128), in view of Clancy et al (U.S. 2004/0057965 A1), and further in view of the SIGMA Catalog (Biochemicals and Reagents for life science, 2000-2001, Adjuvants, pages 1472).

Claims 22 and 23 are drawn to a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering to the animal an effective amount of a vaccine composition containing *E. coli* O157:H7, wherein the vaccine composition comprises inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant and optionally a pharmaceutically acceptable carrier.

Doyle et al teaches a method for reducing shedding of *E. coli* O157:H7 in an animal by administering an effective amount of *E. coli* O157:H7 to infected animals (column 5, lines 58-61). Moreover, Doyle et al teaches the administration of a strain or combination of probiotic bacteria (column 2, lines 61-67). Doyle et al does not teach a vaccine specifically comprising inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant or an effective amount of *Lactobacillus acidophilus.*

Clancy et al teaches a method for the treatment of mucosal infections which comprises administering compositions to any potential surface pathogen (i.e. the intestinal tract; 0015, 0017). Clancy et al teaches that the mucosally administrable compositions comprises one or more antigens derived from at least one microorganism which is capable of causing infection at a mucosal surface and a probiotic. The microorganism is a whole killed, live or live attenuated microorganism (0005-6). Clancy et al teaches that an affective amount is from about $1x10^8$ to about $1x10^{12}$ (0025).

Moreover, the composition may be combined with known pharmaceutically acceptable carriers, solvents and excipients (0008). A preferred probiotic to be used in the composition is *Lactobacillus acidophilus* among others (0009). Lastly, Clancy et al teaches that a range of suitable pharmaceutical adjuvants can be used and would be well known to those skilled in the field of pharmaceutical formulations. Clancy et al does not specifically teach a metabolizable oil adjuvant.

The Sigma catalog teaches commonly used adjuvants, which include but are not limited to squalene, which is a metabolizable oil (1472).

Doyle et al and Clancy et al teach analogous inventions related to methods for treating infections of the intestinal tract by administering a composition, which comprises an antigen, a probiotic and optionally a pharmaceutical carrier. It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to modify the invention of Doyle et al with the teaching of Clancy et al because Clancy et al teaches combining whole killed microorganism together with an adjuvant and a probiotic. Moreover, it would be obvious to modify the invention of Doyle et al and Clancy et al with the Sigma catalog because the Sigma catalog teaches commonly used commercial adjuvants that are used to enhance an immune response. It would have been expected, barring evidence to the contrary, that the method would be effective in reducing the shedding of *E. coli* O157:H7.

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle et al (U.S. Patent 5,965,128), in view of Clancy et al (U.S. 2004/0057965 A1), and further

in view of the SIGMA Catalog (Biochemicals and Reagents for life science, 2000-2001, Adjuvants, 1472) as applied to claims 22 and 23 above, and further in view of Molly et al (U.S. 2005/0084500 A1).

Claim 23 is drawn to a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering to the animal an effective amount of a vaccine composition containing *E. coli* O157:H7, wherein the vaccine composition comprises inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant, optionally a pharmaceutically acceptable carrier and further comprising a neomycin medicated feed supplement to animals.

The teachings of Doyle et al, in view of Clancy et al, and further in view of SIGMA have been taught above. Neither of them teach administering a neomycin medicated feed supplement to an animal.

Molly et al teaches a method for improving the gastrointestinal tract by enumerating enteric pathogens such as *Escherichia* (0059). The method is accomplished by administering useful compositions, which comprises an animal feed antibiotic including but not limited to neomycin (0036). Moreover, Molly et al teaches that the composition can be suitable for the improvement of intestinal function and when fed to dairy animals such as cows, goats and ewes can improve milk production (0047).

In view of all of the above, it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to modify the invention of Doyle et al with the teachings of Clancy et al and with the teachings of the Sigma catalog with the teachings of Molly et al because the composition of Molly et al helps

with the improvement of nutrient replenishment digestion and absorption as well as disease prevention. It would have been expected, barring evidence to the contrary, that the method would be effective in reducing the shedding of *E. coli* O157:H7.

5. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (Effect of dairy calves with an inactivated *E. coli* O157:H7 bacterin on shedding of *E. coli* O157:H7, 1999; Abstract 40 aP), in view of SIGMA (Biochemicals and Reagents for life science, 2000-2001, Adjuvants, 1472).

Claim 22 is drawn to a method for reducing shedding of *E. coli* O157:H7 in an animal which comprises administering to the animal an effective amount of a vaccine composition containing *E. coli* O157:H7, wherein the vaccine composition comprises inactivated or killed whole *E. coli* O157:H7, a metabolizable oil adjuvant and optionally a pharmaceutically acceptable carrier.

Johnson et al teaches a method of vaccination calves with 10^{10} CFU of inactivated *E. coli* O157:H7 bacterin to reduce the shedding of the organism. Johnson et al does not teach a metabolizable oil adjuvant or the optional pharmaceutically acceptable carrier.

The Sigma catalog teaches commonly used adjuvants include but are limited to squalene, which is a metabolizable oil (1472).

It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to modify the invention of Johnson et al with the teaching the Sigma catalog because it is obvious to add an adjuvant to vaccine because

they are used to enhance an immune response and the Sigma catalog teaches commonly used commercial adjuvants. It would have been expected, barring evidence to the contrary, that the method would be effective in reducing the shedding of *E. coli* O157:H7. Limitations such as "optionally" are being viewed as a limitations that may or may not be present in the prior art.

Conclusion

6. No claims are allowed.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ivey et al (U.S. 2004/0052895 A1).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
6/14/06

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